SEP 30 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 30, 2011
Submitter:	GE Healthcare, (GE Healthcare Japan Corporation) 7-127, Asahigaoka 4-chome, Hino-shi, Tokyo 191-8503 JAPAN
Primary Contact Person:	Toru Shimizu Regulatory Affairs Specialist GE Healthcare, (GE Healthcare Japan Corporation) Telephone: +81-42-585-5344 Fax: +81-42-585-5075
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Telephone: (262) 521-6848 Fax: (262) 521-6439
Device: Trade Name:	Discovery MR750w 3.0T
Common/Usual Name:	Magnetic Resonance Imaging System
Classification Names: Product Code:	Magnetic resonance diagnostic device LNH
Predicate Device(s):	Discovery MR750 (K081028) Optima MR450w (K091536)
Device Description:	The Discovery MR750w 3.0T features a superconducting magnet operating at 3.0 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The RF technology of the Discovery MR750w system integrates an RF transmit architecture designed to improve the overall image uniformity. This technology, called Multi-drive, optimizes RF transmit by adjusting the amplitude and phase of the RF output depending on the anatomy being scanned. In order to support Multi-Drive, the RF Transmit (Tx) chain is changed from

MR750 and both Tx lines are divided into 2 lines with Dual output Exciter, Dual output RF amp, Dual Transmit/Receive Switch (DTRSW), dual UPM and a 70cm-wide patient bore RF body coil.

The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Discovery MR750w 3.0T is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use: The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology: The Discovery MR750w 3.0T employs the same fundamental scientific technology as its predicate devices of Discovery MR750 and Optima MR450w. Refer to Section 12 for details of the Technical Comparison Table and the Application/Feature Comparison Chart.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:
As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured and documented through testing to NEMA, IEC or ISO standards as referenced throughout this submission and listed in Section 9:

Performance:

- Signal-to-noise ratio (SNR)
- Geometric distortion
- Image uniformity
- Slice thickness
- Spatial resolution

Safety:

- Static field strength
- Acoustic noise
- dB/dt
- RF heating (SAR)
- Biocompatibility

The tests outlined above have been executed with acceptable results. Refer to Section 15, 18 of this submission for the above performance and safety testing results.

The Discovery MR750w 3.0T has been designed to comply with applicable IEC standards as reference to Section 9, 17.

The device has been tested by a Nationally Recognized Testing Laboratory and certified to conform to applicable IEC, UL and CSA standards prior to commercialization of the system.

Numerical simulations were conducted to demonstrate the safety of the Multi-Drive RF transmit system.

The following quality assurance measures were applied to the development of the system as reference to Section 11, 16, 18:

- Risk Analysis and control
- Requirements Reviews
- Design Reviews
- Design Verification
- Performance and Safety testing (Verification)

Summary of Clinical Tests:

Clinical images and clinical results summary demonstrate that the Discovery MR750w 3.0T maintains the same imaging performance results as the predicate systems of Discovery MR750, Optima MR450w. Refer to Section 20 for details of the studies performed.

Conclusion: GE Healthcare considers the Discovery MR750w 3.0T to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Toru Shimizu
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Hino-Shi, Tokyo, 191-8503
JAPAN

SEP 30 2011

Re: K103327
Trade/Device Name: Discovery MR750w 3.0T System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI and MOS
Dated: September 2, 2011
Received: September 7, 2011

Dear Mr. Shimizu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K103327

510(k) Number (if known): K103327

Device Name: Discovery MR750w 3.0T

Indications for Use:

The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____